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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/538,837	YAMASHITA ET AL.	
	Examiner	Art Unit	
	JAMES H. ALSTRUM ACEVEDO	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *1-5 and 10-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-9* is/are rejected.

7)☒ Claim(s) *6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-22 are pending. It is noted that claims 14-22 do not currently recite statutory subject matter. Claims 1-5 and 10-22 remain withdrawn from consideration as being drawn to non-elected subject matter. **Claims 6-9 are under consideration in the instant office action**. Applicants amended claims 6 and 8. Receipt and consideration of Applicants' amended claim set, terminal disclaimer, 1.132 declaration, and remarks/arguments, submitted on April 22, 2009 are acknowledged. All rejections not explicitly maintained in the instant office action have been withdrawn per Applicants' claim amendments and/or persuasive arguments.

Terminal Disclaimer(s)

The terminal disclaimer filed on April 22, 2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 7,448,379 (formerly allowed copending Application No. 10/170,339) has been reviewed and is accepted. The terminal disclaimer has been recorded.

Election/Restrictions

The restriction of record is maintained at this time. Claims 1-5 and 10-22 remain withdrawn from consideration.

Consideration of 1.132 Declaration submitted April 22, 2009

Applicants' declaration, signed by all the inventors of the instant application, states that the inventors of the instant application, independently of Shigeru Ibaragi, the fourth inventor

listed on allowed Application No. 10/170,339 (PGPB 2003/0101995), did not contribute to the development of freeze-dried transpulmonary compositions prepared from liquids containing active substance that is not wholly dissolve or that is not dissolved at all. Thus, the instant declaration renders the teachings of US 2003/0101995 that are pertinent to the instant application as being by the same inventive entity and US 2003/0101995 is not available as prior art under 102(a) or 102(e).

/J. R. R./

Supervisory Patent Examiner, Art Unit 1616

Specification

The new abstract of the disclosure is objected to because Applicants' submission does not indicate that the new abstract is a replacement paragraph or indicate the specific changes made by underlining or striking out. See MPEP § 714.03 [R-3] and 37 C.F.R. 1.121.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

Claim 6 is objected to because of the following informalities: the phrase "…in a non-dissolved form, and has:" is repeated serially in lines 4-5 of claim 6. Appropriate correction is required.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 6-8 are rejected under 35 U.S.C. 102(a) as being anticipated by Yang (U.S. Patent No. 6,503,537), as evidenced by Ambrosio et al. (WO 94/14492).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Applicant Claims & Claim Interpretation

Applicants claim a dry powder inhalation system comprising (i) a vessel housing a freeze-dried composition having (a) a non-powder form, (b) a disintegration index of 0.05 or more, and (c) a property of becoming fine particles having a mean aerodynamic diameter of 10 microns or less or a fine particle fraction of 10% or more upon receiving an air impact having an air speed of at least 1 m/sec and an air flow rate of at least 17 ml/sec and (ii) a device comprising (1) a member capable of applying said air impact to the freeze-dried composition in said vessel, and (2) a member for discharging said [non]-powder form freeze-dried composition that has been made into fine particles.

Applicants' description of the composition housed in the vessel as "...has: (i) a non-powder form..." is interpreted to mean that the composition ***comprises*** a non-powder form (e.g.

agglomerates or aggregates), but does not exclude the composition from also comprising powder. This is a reasonable interpretation, because the prior art distinguishes between powders and agglomerates or aggregates (Yang) and "has" is properly interpreted to mean "comprises." A powder is understood to refer to fine solid particulates that are not physically bound to other particulates. Applicants' claims also do not prohibit the vessel from being part of the device or being contained therein.

In Table 3, Yang discloses that an exemplified **aggregate composition comprising mometasone furoate** was administered from an inhaler disclosed by Ambrosio to yield an inhalable dry powder upon dosing characterized by a consistent **fine particle fraction (i.e. an average particle size less than 6.8 microns) of 23-24%** (Table 3: col. 18, lines 1-10; Description of composition characterized in Table 3: col. 16, line 60 through col. 17, line 60). Yang's aggregated composition reads on a composition having a non-powder form. Mometasone furoate is an active ingredient. Aggregates are not powders. The only structural limitation imparted by Applicants' product-by-process freeze-drying limitations is that the composition in the vessel is a solid composition, which is met by Yang's disclosure. Because Yang's composition is the same as the recited composition of Applicants' claimed system, Yang's composition inherently must exhibit the same properties, as evidence by the fact that Yang's exemplified composition has the same fine particle fraction property as the composition recited in Applicants' claims.

Ambrosio is cited herein as evidence that the dry powder inhaler (i.e. device) utilized by Yang contained a vessel (i.e. housing) in which Yang's aggregated composition was stored.

Ambrosio discloses dry powder inhalers comprising a powder housing for holding a supply of powdered material to be dispensed, wherein the powder housing includes an inhalation conduit (180), a nozzle to break up agglomerates (380) (abstract). A nozzle reads on a member for discharging the composition as well as a member capable of applying an air impact to the composition

Claims 6-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Yang (U.S. Patent No. 6,503,537), as evidenced by Ambrosio et al. (WO 94/14492).

Applicants' claims are described above. The disclosures of Yang and Ambrosio are set forth above and herein incorporated by reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yang (U.S. Patent No. 6,503,537) as evidenced by Ambrosio et al. (WO 94/14492) and in view of Piper (U.S. Patent No. 5,533,502).

Applicant Claims

Applicants claim a dry powder inhalation system as described above, wherein the dry powder inhaler device comprises a needle part having a suction flow path, an air introduction flow path, and an inhalation port that communicates with said suction flow path.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Yang's and Ambrosio's teachings have been set forth above. Additional teachings of Ambrosio are set forth herein. Ambrosio teaches various embodiments of the invented dry powder inhaler (DPI), such as in Figure 4, wherein the DPI comprises a mouthpiece, a supply chimney (i.e. an air introduction flow path/suction flow path), a driving body, a reservoir plug (i.e. stopper).

Piper teaches DPI's comprising a medicament receptacle (40) (i.e. a vessel), disposed in a medicament carrier contained within a housing and sealed from the outside environment, wherein a pair **of aerosolization conduits (54 and 56) (i.e. needles) pierce the medicament container seal**, causing the medicament to be entrained in air drawn through **the air inlet conduit (54) (i.e. suction flow path)**, and is delivered to the patient **via the aerosol outlet conduit (56) (i.e. an air introduction flow path) and a mouthpiece (52) (i.e. inhalation port)** (abstract; Figures 3 and 4; col. 5, lines 4-58). Piper's DPI will cause large particles (e.g. agglomerates or aggregates) to impinge on the walls and be broken into smaller particles (col. 5, lines 43-45).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Yang lacks the teaching of a kit comprising a DPI with a needle part. This deficiency is cured by the teachings of Piper.

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been prima facie obvious at the time of the instant invention to combine the teachings of Yang and Piper, because Yang's invented compositions are intended to be administered from a dry powder inhaler, and Piper's DPI is suitably adapted to administer aggregates and/or agglomerates of a solid composition to yield inhalable fine particles. An ordinary skilled artisan would have been motivated to modify the Ambrosio DPI's utilized by Yang to obtain a DPI minimizing the waste of medicament, by preventing non-inhaled

medicament composition from adhering to the internal walls of the DPI. An ordinary skilled artisan would have had a reasonable expectation of successfully combining the teachings of Yang and Piper, because Piper's DPI is adapted to break apart aggregates/agglomerates to yield inhalable fine particles. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 6-9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-18 of copending Application No. 12/427,700 (copending '700). Although the conflicting claims are not identical, they are not

patentably distinct from each other because the claims of copending '700 are a species of the claims of the instant application. Thus the claims are considered to be mutually obvious as explained below. Independent claim 6 of the instant application claims a dry powder inhalation system (i.e. a kit) comprising (i) a vessel (i.e. a container), (ii) a freeze-dried composition in a non-powder form contained with the vessel and (iii) a device capable of applying air impact to the freeze-dried composition contained in said vessel to generate fine particles. Independent claim 15 of copending '700 is identical with claim 6 of the instant application, except for the recitation that the freeze-dried composition is freeze-dried interferon-gamma and that the composition is characterized by an overlapping disintegration index range. It is noted that interferon-gamma is a drug and Applicants' claims do not preclude drugs, as evidenced by dependent claim 8 of the instant application, which recites that the freeze-dried composition comprising a drug as an active ingredient. Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 6-9 *prima facie* obvious over claims 15-18 of copending '700.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Vaghefi is considered relevant, because Vaghefi teaches dry powder inhalers that utilize a needle (i.e. piercing nozzle 56) to expose a solid medicament composition that is subsequently inhaled by a user.

Claims 6-9 are rejected. Claim 6 is objected. Claims 1-5 and 10-22 are withdrawn from consideration. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, ~10:00-6:00 and Saturdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/James H Alstrum-Acevedo/
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